

Food and Drug Administration, HHS

§ 520.1044b

electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 14647, Apr. 7, 1978, as amended at 47 FR 15327, Apr. 9, 1982]

§ 520.1010c Furosemide syrup.

(a) *Specifications.* Each milliliter of syrup contains 10 milligrams of furosemide.

(b) *Sponsor.* See. No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 1 to 2 milliliters orally (10 to 20 milligrams) per 10 pounds of body weight (approximately 2.5 to 5 milligrams per kilogram), once or twice daily, with a 6- to 8-hour interval between successive daily doses.

(2) *Indications for use.* It is used in dogs for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(3) *Limitations.* The dosage should be adjusted to the animal's response. In severe edematous or refractory cases, the dosage may be doubled or increased by increments of 1 milligram per pound of body weight to establish the effective dose. This dose should be administered once or twice daily on an intermittent schedule. Diuretic therapy should be discontinued after reduction of edema or, when necessary, maintained after determining a programmed dosage schedule to prevent recurrence. If given in excessive amounts or over extended periods of time, the drug may result in dehydration and/or electrolyte imbalance. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 11177, Mar. 17, 1978, as amended at 47 FR 15327, Apr. 9, 1982]

§ 520.1044 Gentamicin sulfate oral dosage forms.

§ 520.1044a Gentamicin sulfate oral solution.

(a) *Specifications.* Each milliliter of aqueous solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use—(1) Amount.* Colibacillosis: 1 milliliter per 2 gallons of drinking water for 3 consecutive days, to provide 0.5 milligram/pound/day; swine dysentery: 1 milliliter per 1 gallon of drinking water for 3 consecutive days, to provide 1.0 milligram/pound/day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 3 days following treatment.

[48 FR 10302, Mar. 11, 1983. Redesignated at 49 FR 572, Jan. 5, 1984, and amended at 49 FR 14332, Apr. 11, 1984; 52 FR 7832, Mar. 13, 1987; 62 FR 34169, June 25, 1997]

§ 520.1044b Gentamicin sulfate pig pump oral solution.

(a) *Specifications.* Each milliliter of pig pump oral solution contains gentamicin sulfate equivalent to 4.35 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use—(1) Amount.* Administer 1.15 milliliters of pig pump oral solution (5 milligrams of gentamicin) orally per pig one time.

(2) *Indications for use.* In neonatal swine 1 to 3 days of age for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(3) *Limitations.* For use in neonatal swine only. Do not slaughter treated swine for food for at least 14 days following treatment.

[49 FR 572, Jan. 5, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 29011, May 29, 1997]